

APPLICATION GAT ON FORRMARIZATION OF FACILITIES WATERIER POSITION OR FACILITIES OF THE PROPERTY OF THE PROPERT



| Registra | ation Number | |
|----------------------------|---|--|
| Date of submission of the | | |
| dossier | | |
| Number of files | | |
| Name of Assessor | | |
| Date of Assessment | | |
| Outcome of the assessment | | |
| 1.0 ADMINISTRATIVE INFORMA | | RMATION |
| 1.1 | Type of the product a | pplication (tick as appropriate) |
| | Antiseptic | |
| | Disinfectant | |
| | Medicated Soap | |
| 1.2 | Proprietary Name of the product | |
| 1.3 | Generic name of the product | |
| 1.4 | Name and strength o | f active substance(s) |
| 1.5 | Name and address (physical and postal) of Applicant | |
| (Compa | ıny) Name: | |
| Address | S: | |
| Country | | |
| Telepho | | |
| Telefax | • | |
| E-Mail: | | |
| 1.5.1 | Form of the product: | |
| | ☐Gaseous ☐Powde | er Bar Tablet Cream Others – specify |
| 1.5.2 | Intended use: | |
| 1.6 | Packing/pack size: | |
| 1.7 | Visual description | |
| 1.8 | Proposed shelf life (in months): | |
| 1.8.1 | Proposed shelf life (after reconstitution or dilution): | |
| 1.8.2 | Proposed shelf life (after first opening container): | |
| 1.8.3 | Proposed storage co | |
| 1.8.4 | Proposed storage co | nditions after first opening: |
| 1. 9 | Country of manufacture: | |
| 1.10 | Name(s) and physica | al address (es) of the manufacturing site of the finished product. |



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| Company name: Physical address: Postal address: Country: Telephone: | | | |
|--|---|--|--|
| Telefax: E-Mail: | | | |
| L-Iviali. | | | |
| 2.0 VARIATIONS | | | |
| 2.1 Changes made to the product | | | |
| 2 Description of the changes | | | |
| 2.3 Justification for changes | | | |
| 3.0 DECLARATION BY AN APPLICANT | | | |
| I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. It is hereby confirmed that fees will be paid/have been paid according to the TFDA fees and regulation Name: Position in the company: Signature: Date: Official stamp: | ; | | |
| * Note: If fees have been paid, attach proof of payment | | | |